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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/165,460 10/02/98 RINE

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EXAMINER

THUNG, P

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

18

08/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/165,460

Applicant(s)
Rine et al.

Examiner
Peter Tung

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-46 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. Claims 31-46 are pending.
2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 32 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant expression vector comprising a polynucleotide which hybridizes to SEQ ID NO:1 or 3 and which encodes a polypeptide of SEQ ID NO: 2 or 4, respectively, and wherein the polynucleotide contained on the expression vector encodes a polypeptide which the proteolytic removal of an AAX tripeptide from a prenylated CAAX protein, does not reasonably provide enablement for a recombinant expression vector comprising a polynucleotide which hybridizes to SEQ ID NO:1 or 3 and which encodes conservatively modified SEQ ID NO: 2 or SEQ ID NO: 4, respectively. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement

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requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The breadth of the claims encompasses any conservative modifications to SEQ ID NO: 2 or 4. Insufficient guidance and examples are provided on where conservative amino acid modifications could be made to SEQ ID NO: 2 or 4 without affecting enzymatic function. As there is unpredictability in the art in making even conservative substitutions in a protein sequence without affecting its structure and function, the level of skill in the art is low in making a polynucleotide which would hybridize to a nucleic acid encoding a conservatively modified SEQ ID NO: 2 or 4. Undue experimentation would be required to enable the full scope of the claims based upon the limited scope of the disclosure.

5. Claims 32 and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is explained in the previous Office action.
6. Applicants argue that the amended claims avoid this rejection and are in the enabled scope.

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7. Applicant's arguments filed 4/3/01 have been fully considered but they are not persuasive.

As amended, the claims are still rejected.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 31-34 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al. in view of Nozaki et al. (U.S. Patent No. 4,997,767). This rejection is explained in the previous Office action.

10. Applicants argue that the creation date relied on by the Examiner for the public availability of Rose et al. is not reliable and therefore the reference, with a listed date of Aug. 11, 1997, is not prior art. Applicant argues that there is no assurance that the information in the cited reference has not been modified since its listed date of Aug. 11, 1997 as opposed to the create date of 10/6/95. Applicants argue that no evidence was provided that the relied upon sequence was presented to GenBank or created or published at any time prior to Aug. 11, 1997. Applicants argue that it is the duty of the Examiner to allow claims unless the Examiner can establish a prima facie case of non-patentability, which includes showing that the cited art is prior art. Applicants

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further argue that while the entire yeast genome has been largely sequenced prior to the instant application filing, and that open reading frames have been identified, the claimed compositions would neither be anticipated or obvious. Applicants argue that the instant claims require that the coding sequence be operatively joined to a promoter and that with the absence of any evidence for function, there would be no motivation to select out one of the thousands of yeast ORFs of unknown function, which may or may not be a coding sequence, and operatively join to a promoter.

11. Applicant's arguments filed 4/3/01 have been fully considered but they are not persuasive. The Examiner has provided evidence in the NCBI database of a creation date which is asserted in the Office action as the public availability date. The rejection in the last Office action citing the Rose et al. reference and providing the public availability date is a prima facie case. It is the responsibility of the Applicants to demonstrate that such a public availability date of 10/6/95 did not include the cited sequences. Furthermore, once a sequence is known and an open reading frame identified, one of ordinary skill in the art would be motivated to characterize the protein encoded by the open reading frame. Placing such a sequence in an expression vector would have been obvious to one of ordinary skill. That there may be thousands of ORFs with unknown function does not remove the motivation to place an ORF sequence into an expression vector to characterize the protein.

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12. Claims 35-38 and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lye et al. in view of Nozaki et al. (U.S. Patent No. 4,997,767). This rejection is explained in the previous Office action.

13. Applicants argue that the Lye et al. reference has a date of Aug. 11, 1997 and is therefore not prior art. Applicants argue that if a database does not have a publication date, it cannot be relied upon as prior art. Applicants argue that the Examiner is depending upon a purported unpublished submission date for the Lye et al. reference and that no evidence has been offered that the relied upon sequence was published any time prior to Aug. 11, 1997. Applicants further argue that Lye discloses computer predictions of thousands of possible coding sequences and does not disclose any gene or gene product. Applicants argue that the Examiner uses Applicants own disclosure to select one of many *Saccharomyces* genes and Applicants disclosure to provide motivation to recombine it in an expression vector. Applicants argue that absent any evidence of function, there would be no motivation to select out one of the thousands of yeast ORFs of unknown function.

14. Applicant's arguments filed 4/3/01 have been fully considered but they are not persuasive. A publication date is needed to indicate when a database is publicly available. As stated in the previous Office action, the Lye et al. has a public availability date of 5/16/95. The rejection in the last Office action citing the Lye et al. reference and providing the public availability date is a prima facie case to which Applicants must now demonstrate with evidence as to why Lye et al. is not a

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prior art reference. Furthermore, once a sequence is known and an open reading frame identified, one of ordinary skill in the art would be motivated to characterize the protein encoded by the open reading frame. Placing such a sequence in an expression vector would have been obvious to one of ordinary skill. That there may be thousands of ORFs with unknown function does not remove the motivation to place an ORF sequence into an expression vector to characterize the protein. In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper use of Applicants own disclosure, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Additionally, the motivation provided by the examiner is not the same motivation disclosed.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

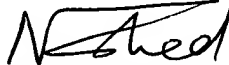
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER